

REMARKS

Claims 1 and 3-20 are pending in the present application.

The rejection of Claims 2-4 and 6-7 under 35 U.S.C. §103(a) over Cavanaugh, Jr. in view of O'Connor et al is respectfully traversed.

Cavanaugh, Jr. is cited as providing a general disclosure of NSAIDs as well as their pH and concentrations. Column 1, lines 44-65 of Cavanaugh, Jr. is referenced by the Examiner as qualifying diclofenac as a NSAID. With respect to the pH, the Examiner points to column 5, lines 24-27 of Cavanaugh, Jr., where it is disclosed that the pH of the compositions disclosed therein can range from about 2 to about 9. In regard to the concentration of the NSAID, the Examiner points to column 5, lines 10-15 of Cavanaugh, Jr., which discloses that the concentration may generally be from about 0.02% to about 4%.

Applicants submit that it is inappropriate to consider diclofenac as a NSAID within the scope of the disclosure of Cavanaugh, Jr. as the inventors themselves do not appear to treat this compound as such. The Examiner is correct in that column 1, lines 44-65 of Cavanaugh, Jr. does state that diclofenac is a NSAID; however, diclofenac is not included in the list of NSAIDs appearing at column 3, lines 10-19 and Claim 2. In fact, Cavanaugh, Jr. makes it quite clear that his disclosure is substantially related to ketorolac. Further, it should be noted that the only recitation of diclofenac appears at column 1, line 52.

Accordingly, Applicants submit that there is no motivation or suggestion provided by Cavanaugh, Jr. to select diclofenac as a NSAID or to apply the very generally described pH and concentrations. Moreover, even if the skilled artisan did select diclofenac, this is only the first step toward the claimed invention as the artisan would then have to substantially narrow the pH and concentration disclosed by Cavanaugh, Jr. without any guidance therein to arrive

at the specifically claimed combinations of: (a) a concentration of 0.1% (w/w) at a pH ranging from 7 to 8 (see Claim 1), or (b) a concentration ranging from 0.1% to 0.2% (w/w) at a pH ranging from 7.6 to 8 (see Claim 11).

The lack of sufficient motivation to arrive at these combinations based on the disclosure of Cavanaugh, Jr. is underscored by looking at the preferred embodiments of his invention. With respect to concentration, at column 5, lines 13-14 of Cavanaugh, Jr. this reference specifically states that the most preferred concentration is from about 0.2% to about 0.8%, which is greater than the concentration in Claim 1 and only shares a common end-point with Claim 11. In regard to pH, at column 5, line 27 of Cavanaugh, Jr. this reference specifically states that the most preferred pH is from about 5 to about 6 (i.e., an acidic pH). In contrast, the pH in both Claims 1 and 11 are considerably more basic (i.e., has a higher pH).

In citing O'Connor et al, it appears that the Examiner recognizes the aforementioned deficiencies in the disclosure of Cavanaugh, Jr. Specifically, in the last paragraph on page 9 of the Office Action mailed July 15, 2005, the Examiner acknowledges that Cavanaugh, Jr. "does not specifically teach providing a composition having an NSID that is diclofenac in the percent concentration and pH ranges recited in the claim[s]." The Examiner then further alleges that O'Connor et al is applied for the reasons specified in the anticipation rejection of original Claim 1 and 8. Applicants submit that in view of the present amendment, O'Connor et al fails to compensate for the deficiency in the disclosure of Cavanaugh, Jr.

As stated below, O'Connor et al disclose a salt of diclofenac and tromethamine at a pH of 7.13. Further, O'Connor et al reports that the solubility of the diclofenac/tromethamine salt is 3.95 mM, which corresponds to 0.16% (w/w). Applicants have amended Claim 1 to limit the amount of the salt to that previously set forth in Claim 2, which the Examiner

recognizes as being free from the disclosure of O'Connor et al. Further, new Claims 11-20 have been presented in which the pH is defined as being 7.6 to 8. Clearly the disclosure of O'Connor et al fails to disclose this pH range.

Furthermore, Applicants submit that the present invention offers certain advantages when the specifically claimed combination of concentrations and pHs is observed. As shown in Examples 1-4, the specifically claimed combination of concentrations and pHs affords enhanced stability as compared to compositions failing meet this limitation. Applicants submit that Cavanaugh, Jr. and O'Connor et al do not offer a suggestion of this result.

Accordingly, the combined disclosures of Cavanaugh, Jr. and O'Connor et al fail to specifically direct the artisan to make the four required steps from the disclosure of Cavanaugh, Jr. to the invention as claimed. First, the artisan would have to select diclofenac as a NSAID. Second, the artisan would have to select the specifically claimed concentration or concentration range. Third, the artisan would have to select the specifically claimed pH ranges. Fourth, the artisan would have to properly combine the selected concentration and the pH per the specifically claimed invention. Applicants submit that there is absolutely nothing in the disclosures of Cavanaugh, Jr. and O'Connor et al to direct such a selection process. Applicants kindly ask that the Office not use their disclosure as a guidepost to piece together their invention from the deficient disclosures of Cavanaugh, Jr. and O'Connor et al. The question that the Examiner should ask is why, absent Applicants' disclosure, would the artisan be motivated to arrive at the present invention when neither Cavanaugh, Jr. nor O'Connor et al sufficiently specify that which Applicants have invented?

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

The rejection of Claim 5 under 35 U.S.C. §103(a) over Cavanaugh, Jr. in view of O'Connor et al and Bianchi et al is respectfully traversed.

Cavanaugh, Jr. and O'Connor et al have been discussed above in relation to independent Claims 1 and 11. Bianchi et al is cited for its disclosure of an aqueous-based dentifrice composition containing a polyoxyethylene polyoxypropylene block copolymer. However, Applicants submit that Bianchi et al fails to compensate for the aforementioned deficiencies in the combined disclosures of Cavanaugh, Jr. and O'Connor et al. Accordingly, the combined disclosures of Cavanaugh, Jr., O'Connor et al, and Bianchi et al fails to render the present invention obvious.

Applicants request withdrawal of this ground of rejection.

The rejection of Claims 1 and 8 under 35 U.S.C. §102(b) over O'Connor et al is obviated by amendment.

As indicated by the Examiner, O'Connor et al disclose a salt of diclofenac and tromethamine at a pH of 7.13. Further, O'Connor et al reports that the solubility of the diclofenac/tromethamine salt is 3.95 mM, which corresponds to 0.16% (w/w). Applicants have amended Claim 1 to limit the amount of the salt to that previously set forth in Claim 2, which the Examiner recognizes as being free from the disclosure of O'Connor et al. In view of this amendment, Applicants submit that Claims 1 and 8 are not anticipated by O'Connor et al. Further, new Claims 11-20 have been presented in which the pH is defined as being 7.6 to 8. Clearly the disclosure of O'Connor et al fails to disclose this pH range. As such, Claims 11-20 are free from the disclosure of O'Connor et al.

Applicants request withdrawal of this ground of rejection.

The rejection of Claim 8 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

Applicants have amended Claim 8 to be a method of using the composition of Claim

1. As such, Claim 8 defines an invention of different scope than Claim 1.

Applicants request withdrawal of this ground of rejection.

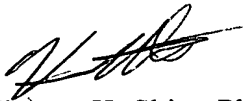
The objection to the specification is obviated by the present amendments. Applicants have amended the specification to insert the appropriate section headings. Withdrawal of this ground of objection is requested.

The objection to Claims 4-8 under 37 C.F.R. §1.75(c) is obviated by amendment. Applicants have amended the claims to remove the multiple dependencies. Withdrawal of this ground of objection is requested.

Applicants submit that the present application is now in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

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